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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,995	09/17/2003	Kevin R. Seifert	P-11309.0	4609

27581 7590 04/21/2006

MEDTRONIC, INC.  
710 MEDTRONIC PARK  
MINNEAPOLIS, MN 55432-9924

EXAMINER
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LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,995	<b>Applicant(s)</b> SEIFERT ET AL.	
	<b>Examiner</b> Carl H. Layno	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,9,10,15 and 16 is/are rejected.
- 7) ☒ Claim(s) 2,4,6-8 and 11-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/8/04, 3/3/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for priority as a Continuation-In-Part (CIP) of U.S. Application Serial No. 10/637,160, filed on August 8, 2003.

### ***Information Disclosure Statement***

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449s), which were received by the Office on April 8, 2004 and on March 3, 2005.

### ***Specification***

3. The disclosure is objected to because of the following informalities:
  - p.4, lines 6 and 7, the element "12" appears to be numbered "120" in Figs.1B and 2A, and
  - p.11, line 1, distal end "672" appears to be a typo. This should be "627" to be consistent with Fig.11.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1, 9, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Swoyer et al (US 6,754,536).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In regard to claims 1, 9, and 10, the Swoyer et al (US 6,754,536) patent describes an impenetrable medical electrical lead (Fig.2) comprising a lead body 40/42, including a distal end 54, a first electrode 44, an elongated conductor 70 (Fig.4) within elongated flexible member 50, and a distally located second portion 64 (Fig.2) mounting a second electrode 60 with a helix

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tissue anchor **62**. Helix **62** may be, alternatively, a stimulation /sense electrode (col.10, lines 35-36).

In regards to claims 9 and 10, applicant's attention is directed to Fig.6, which shows the use of a "push member" **80** (col.9, lines 62-64) may be temporarily attached to the end of element lead body **42** to move it into position within the body. The use of a modified lead body **42** or second portion **64** to receive the end of push member **80** is inherent.

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 5, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoyer et al (US 6,754,536) in view of Spehr (US 5,851,227).

In regard to claims 3, 5, and 15, although the device of Swoyer et al specifies the use of a helix anchor **62** for attachment to the heart of a patient, to have specified horizontal tines would have been an obvious selection to one of ordinary skill in view of the teachings of Spehr (US. 5,851,227), which discloses a number of embodiments showing different anchoring mechanisms used on the distal end of cardiac leads. These include both helix anchors (Figs. 8 and 10) and tined anchors (Fig.7).

In regard to claim 16, Figs. 7, 8, and 10 of Spehr teach the use of an insertion stylet **86** including a distal end, which is received within a recess **66** in the portion of the device having a tissue anchor.

***Allowable Subject Matter***

8. Claims 2, 4, 6-8, and 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CARL LAYNO  
PRIMARY EXAMINER

CHL  
4/17/2006